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| 10/736,455 | 12/15/2003 | Dimitris N. Metaxas | 7557/21 | 3096 |
| 27614 7590 12/13/2007 MCCARTER & ENGLISH, LLP FOUR GATEWAY CENTER 100 MULBERRY STREET NEWARK, NJ 07102 | | | EXAMINER SHIKHMAN, MAX | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/736,455

Applicant(s)

METAXAS ET AL.

Examiner

Max Shikhman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/11/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 21-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-13 is/are allowed.
- 6) ☒ Claim(s) 14-17, 23-34, 36-44, 47-49 is/are rejected.
- 7) ☒ Claim(s) 21, 22, 35, 45 and 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/11/2007.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

EXAMINER'S AMENDMENT

Please replace in Claim 21 line 1, "20" to --14--.

Response to Amendment

1. Applicants' response to the last Office Action, filed 10/11/2007 has been entered and made of record.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims **14,27,38,42,43,44; 15, 39; 16,30,40; 17,41; 23, 36, 47; 24, 48; 28, 29, 31, 32, 33, 34** are rejected under 35 U.S.C. 103(a) as being unpatentable over

Kinnard, "Separation of malignant and benign masses using maximum-likelihood modeling and neural networks", SPIE Volume 4684 May 2002, pp. 733-741 in view of

Hibbard (US-PAT-NO: 6249594) and further in view of

Gonzalez, "Digital Image Processing, 2/E" (ISBN-10: 0201180758, Published: 11/09/2001).

() Regarding Claims 14, 42, 43, 44:

14. *(Currently Amended) An apparatus for automatically detecting breast tumors and lesions in an image comprising:*

a scanner for generating an image of a breast; (Kinnard. Abstract: Mammogram)

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texture and intensity (Abstract, "intensity, shape, and texture features". P736 last line, "texture features". P734 "grayscale level or texture.")

classifiers applied to each pixel of the image, (P737 Section 2.3)

the classifiers (P737: Section 2.3 "Classifiers")

corresponding to probabilities (P_i . P736 "joint probability matrix $P_{d,\theta}(i, j)$.)

of the pixel belonging to a lesion or tumor; (P735, "determine the likelihood that the contour represents the tumor body by assessing the maximum likelihood function")

means for determining a seed point in the image, (P734 "seed point") *wherein said means retrieves a set of points of interest* ("region of interest") *in the image, selects a first point from the set of points*, (P734 "region of interest begins as a single pixel")

and calculates a joint probability (P736 "joint probability matrix $P_{d,\theta}(i, j)$.) *that the first point corresponds to a tumor*;

means for growing a region of interest around the seed point; (P734 "region of interest begins as a single pixel and grows")

Kinnard discloses everything as described above except, *a filter for filtering the image; means for calculating directional gradients for each pixel in the image; means for determining boundary points of the region of interest using the directional gradients; and a deformable model for processing the boundary points to determine the presence or absence of a tumor or lesion in the image.*

Hibbard discloses, *means for calculating directional gradients for each pixel in the image;*

(Hibbard. Gradients have been pre-computed as I_g .)

Column 7, lined 8-10, "objective function is in the form $M(p, I_g, I_r)$, ... I_g is the gray-level gradient image," Column 12, line 57 shows I_g .)

means for determining boundary points of the region of interest using the directional gradients; and (Col 6 line 61, "the coincidence of the boundary with the local gray level gradient". Col 8 line 17, "boundary contours optimally match the local image gray level gradients". Col 14 line 35. Col 16 line 63, "The likelihood of p representing the true boundary is proportional to the sum of the gradient...")

a deformable model for processing the boundary points ("Contour". Also, Col 16 lines 39-46)

to determine the presence or absence of a tumor or lesion in the image. (Col 3 line 1, "tumors". Col 6 line 2 "objects")

As Hibbard discloses, it is desirable to use gradients to find optimal contours of anatomical objects, including tumor. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use Hibbards' method of taking a gradients of an image (Col 12 line 57: I_g) to find contours, in the method of Kinnard, to segment tumors in Kinnard.

Kinnard and Hibbard disclose everything except *a filter for filtering the image*.

Gonzalez discloses, *a filter for filtering the image*.

Gonzalez discusses many kinds of filters; mean image filters on page 231. As Gonzalez discloses, it is desirable to implement a simple mean image filter to reduce image noise. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention, to use Gonzalez' method in the combined method of Kinnard and Hibbard—use a mean filter to reduce image noise. Reducing image noise improves visual image quality.

() Regarding Claims 15, 39:

The apparatus of claim 14, wherein the scanner comprises an analog mammogram scanner, a digital mammogram scanner, an ultrasound scanner, or an MRI scanner.

(Hibbard. ABSTRACT: "A system and method is disclosed for automatically computing contours representing the boundaries of objects in three-dimensional tomographic images that may be formed by computed tomography ("CT"), magnetic resonance imaging ("MRI").)

() Regarding Claims 16, 30, 40:

Hibbard discloses all of the subject matter as described above except, *"filter comprises a Butterworth filter for removing speckle from the image."*

Gonzalez discloses Butterworth LPF on pages 173-175, HPF on page 183, and Bandreject on page 244. Page 245, Figure 5.16, shows a Butterworth de-noised image.

It is desirable to de-noise the image for better viewing. Therefore it would have

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been obvious to one of ordinary skill in the art at the time of the invention, to modify Hibbard's method with Gonzalez and de-noise an image using a Butterworth filter, for better viewing.

() Regarding Claims 17, 41:

The apparatus of claim 14, wherein the texture and intensity classifiers (Kinnard P737 Section 2.3) are generated by texture and intensity probability distribution functions applied to pixels of the image. (P736 "joint probability matrix $P_{d,e}(i, j)$.)

() Regarding Claims 23, 36, 47:

23. The apparatus of claim 14, wherein the means for growing the region of interest adds the seed point to the region of interest (Kinnard. P734 "region of interest begins as a single pixel and grows")

and adds pixels to the region of interest based upon connectivity and values of surrounding pixels.

(P734, "The next 4- or 8-neighboring pixel is checked for similarity so that the region can grow.")

() Regarding Claims 24, 48:

Kinnard and Hibbard discloses all of the subject matter as described above except, *"The apparatus of claim 14, wherein the means for determining boundary points scans the region of interest horizontally and vertically to determine edge points, and combines the edge points."*

Gonzalez discloses, Page 585-587, Figure 10.16. Take horizontal gradient of the image. Take a vertical gradient of the image. Form a final image using edge linking. It

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is desirable to detect horizontal and vertical image edges. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention, to modify Kinnard and Hibbard with Gonzalez. Take vertical and horizontal gradients of an image. Link their edges. As Figure 10.16 on Page 586 shows, this highlights horizontal and vertical edges, which can be used for identification purposes.

() Regarding Claim 27,38:

27. (New) *A method for automatically detecting breast tumors and lesions in art image comprising:*

acquiring an image of a breast; (Kinnard. Abstract: Mammogram)

applying texture and intensity (Abstract, "intensity, shape, and texture features".

P736 last line, "texture features". P734 "grayscale level or texture.")

classifiers to each pixel of the image, (P737 Section 2.3)

the classifiers corresponding to probabilities (Pi. P736 "joint probability matrix $P_{d,\theta}(i, j)$.)

of the pixel belonging to a lesion or tumor; (P735, "determine the likelihood that the contour represents the tumor body by assessing the maximum likelihood function")
determining a seed point in the image; (P734 "seed point")

growing a region of interest around the seed point; (P734 "region of interest begins as a single pixel and grows")

Kinnard discloses everything as described above except,

a) filtering the image; (Gonzalez. Disclosed in Claim 14.)

b) calculating directional gradients for each pixel in the image; (Hibbard in Claim 14.)

c1) determining boundary points of the region of interest using the directional gradients (Hibbard. Disclosed in Claim 14.)

c2) by scanning the region of interest horizontally and vertically to determine edge points, and combining the edge points; (Gonzalez. Disclosed in Claim 24.)

d) drawing radial lines from the seed point and plotting boundary points corresponding to positions of maximum intensity on the radial lines; and (Zahalka. Disclosed in Claim 25.)

e) processing the boundary points with a deformable model to determine the presence or absence of a tumor or lesion in the image. (Hibbard. Disclosed in Claim 14.)

Motivation to combine Kinnard+b+c1+e limitations.

As Hibbard discloses, it is desirable to use gradients to find optimal contours of anatomical objects, including tumor. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use Hibbards' method of taking a gradients of an image (Col 12 line 57: lg) to find contours, in the method of Kinnard, to segment tumors in Kinnard.

Motivation to combine Kinnard+b+c1+e+c2 limitations.

Gonzalez discloses, Page 585-587, Figure 10.16. Take horizontal gradient of the image. Take a vertical gradient of the image. Form a final image using edge linking. It is desirable to detect horizontal and vertical image edges. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention, to modify Kinnard and Hibbard with Gonzalez. Take vertical and horizontal gradients of an image. Link their edges. As Figure 10.16 on Page 586 shows, this highlights horizontal and vertical edges, which can be used for identification purposes.

Motivation to combine Kinnard+b+c1+e+c2+d limitations.

As Zahalka discloses (Fig2), it is desirable to radially extend lines from a seed point to detect boundaries (Col 6 line 24). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to use Zahalka's method in the combined method of Kinnard, Hibbard and Gonzalez. This allows improved boundary detection.

Motivation to combine Kinnard+b+c1+e+c2+d+a limitations.

Gonzalez discloses, *a filter for filtering the image*.

Gonzalez discusses many kinds of filters; mean image filters on page 231. As Gonzalez discloses, it is desirable to implement a simple mean image filter to reduce image noise. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention, to use Gonzalez' method in the combined method of Kinnard and Hibbard—use a mean filter to reduce image noise. Reducing image noise improves visual image quality.

() Regarding Claim 28:

28. (New) *The method of claim 27, wherein the step of acquiring the image comprises digitizing the image from an analog mammogram.*

Gonzalez discloses image sampling in Chapter 2 and in Figure 2.17. A digital mammogram is in Fig 3.4 on page 79. We need to digitize an analog Mammogram image for manipulation and storage inside computer using software executing Kinnard's method. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention, to modify Kinnard's method with Gonzalez; first digitize a mammogram and then auto segment it using a computer. This allows for software image manipulation and storage. Software image manipulation allows for implementation of complex algorithms, like image de-noising, which improves visual image quality.

() Regarding Claim 29:

29. (New) *The method of claim 27, wherein the step of acquiring the image comprises acquiring a digital mammogram, ultrasound, or MRI image of a breast.*

(Kinnard. Abstract: Mammogram)

() Regarding Claim 31:

31. (New) *The method of claim 30, further comprising enhancing contrast of the image.*

Gonzalez discloses "contrast enhancement" on Page 77 and Figure 3.2, Pages 85-86 and Figure 3.10. As shown in Figure 3.10, contrast stretching enhances the image. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention, to modify Kinnard's method with Gonzalez's method of contrast stretching, to enhance contrast in an image.

() Regarding Claim 32:

The method of claim 27, wherein the step of applying texture and intensity classifiers comprises determining intensity (gray level) and local variance (standard deviation) of each pixel of the image.

(Hibbard. Column 11, lines 35-40, "According to Expression (7) the feature vector $X=[x_1, \dots, x_n]$ has as its n-components the numeric values of several gray-level-derived measurements on the set of pixels in a neighborhood about each pixel. ... The numeric

values can include the mean, standard deviation, skewness, kurtosis, energy, entropy, and the range, but also other texture measures.”)

() Regarding Claim 33:

33. (New) The method of claim 32, further comprising applying a texture probability distribution function to the local variance (standard deviation) of the pixel to produce the texture classifier. (Texture classifier is in Column 21, lines 3-14. Column 22, lines 12-20.)

() Regarding Claim 34:

34. (New) The method of claim 32, further comprising applying an intensity probability distribution function to the intensity of the pixel to produce the intensity classifier.

(Hibbard. Column 11, lines 35-40, “According to Expression (7) the feature vector $X=[x_1, \dots, x_n]$ has as its n-components the numeric values of several gray-level-derived measurements on the set of pixels in a neighborhood about each pixel. ... The numeric values can include the mean, standard deviation, skewness, kurtosis, energy, entropy, and the range, but also other texture measures.” Texture classifier uses intensity values.

Kinnard. P735 Equation 3. Fig 2 “intensity choice”)

4. Claims **25, 26, 37, 49** rejected under 35 U.S.C. 103(a) as being unpatentable over Kinnard, "Separation of malignant and benign masses using maximum-likelihood modeling and neural networks", SPIE Volume 4684 May 2002, pp. 733-741 in view of Hibbard US-PAT-NO: 6249594 and in view of Gonzalez, "Digital Image Processing, 2/E" (ISBN-10: 0201180758, Published: 11/09/2001) as applied to Claim 24 above and further in view of Zahalka US-PAT-NO: 6385332.

() Regarding Claim 25:

Kinnard, Hibbard, Gonzalez disclose everything as described above except the limitations of Claim 25.

Zahalka discloses, *The apparatus of claim 24, wherein the means for determining boundary points draws radial lines from the seed point and* (Fig2. Col2 line 50, "rays extending radially from a single seed point for the purpose of edge selection during an automated initial contour identification". Col 5 line 57.)

plots boundary points corresponding to positions of maximum intensity on the radial lines.

(Col 6 lines 19-24, "search is conducted for the maximum intensity along the ray... voxel with maximum intensity, I_m is likely a part of the boundary edge along this ray")

As Zahalka discloses (Fig2), it is desirable to radially extend lines from a seed point to detect boundaries (Col 6 line 24). Therefore it would have been obvious to one

of ordinary skill in the art at the time of the invention to use Zahalka's method in the combined method of Kinnard, Hibbard and Gonzalez. This allows boundary detection.

() Regarding Claim 26, 37, 49:

26. *The apparatus of claim 25, wherein the means for determining the boundary points removes outliers and local maxima from the boundary points.*

(Zahalka. Col 6 line 20. "with the condition... maximum conforms to a trend and is not an isolated noise occurrence.")

Allowable Subject Matter

5. Claims 1-13 allowed.

6. Claims 21, 22, 35, 45, 46 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter: Claim 1 allowable because the prior art of record does not disclose, *determining a seed point in the image by retrieving a set of points of interest in the image, selecting a first point from the set of points, calculating a joint probability that the first point corresponds to a tumor, calculating mean joint probabilities that points in a circular region around the first point correspond to a tumor, and designating a point within the circular region having a maximum mean joint probability as the seed point.* Claims 2-13 are allowed because they depend on allowed Claim 1.

Claim 21 would be allowable because the prior art of record does not disclose, "The apparatus of claim 20, wherein the means for determining the seed point calculates mean joint probabilities that points in a circular region around the first point correspond to a tumor." Claim 22 would be allowable since it depends on Claim 21.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yoshida (US-PAT-NO: 6078680) discloses, "Method, apparatus, and storage medium for detection of nodules in biological tissue using wavelet snakes to characterize features in radiographic images".

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Max Shikhman whose telephone number is (571) 270-1669. The examiner can normally be reached on Monday-Friday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JINGGE WU can be reached on (571) 272-7429. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Max Shikhman
12.6.2007


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